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510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

NOV 19 2007

Contact: Mr. Mohan Emmanuel, President
Implants International, Ltd.,
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Thornby-On-Tees
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Email: mohan.emmanuel@implantsinternational.com

Trade name:	RIGI-FIX™ Hip Stem System
Common name:	Femoral Hip Stem
Classification name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Hip joint metal/polymer/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulation number:	21 CFR 888.3353 - Class II, Orthopedic Device Panel 87
Product Code:	MEH, LPH
Device Description and Characteristics:	The RIGI-FIX™ Hip Stem System is a non-cemented acetabular cup system with a complete assortment of neutral and 10° hooded poly inserts as well as acetabular screws and screw hole covers (screw hole occluders).
Equivalence:	The RIGI-FIX™ Hip Stem System is equivalent to other legally marketed acetabular cup systems in design, materials and intended use. Equivalent devices include the: BIOMET TAPERLOC Femoral Stem (K921301 S/E 2/16/94 and K043537 S/E 1/14/05)
Indications:	The RIGI-FIX™ Hip Stem System is intended for uncemented use for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to femoral hip stem revisions.
Performance data:	Biomechanical tests have been performed. The test results were equivalent to other similar implants and are sufficient for in vivo loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Implants International, Ltd.
% Mr. Mohan Emmanuel
Chief Executive
71 Jay Avenue, Teesside Industrial Estate
Thornaby-on-Tees, Cleveland, TS17 9LZ UK

NOV 19 2007

Re: K072101
Trade Name: RIGI-FIX™ Hip Stem System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LPH
Dated: October 18, 2007
Received: October 22, 2007

Dear Mr. Emmanuel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K072101 (pg 1/1)

Device Name(s):

RIGI-FIX™ Hip Stem System

Indications for Use:

The RIGI-FIX™ Hip Stem System is intended for uncemented use for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to femoral hip stem revisions.

Prescription Use X AND/OR Over-The-Counter-Use _____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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